Testimony
Before the Committee on Government Reform
United States House of Representatives

CDC's Activities to Prevent Hepatitis C Infection

Statement of

Rima Khabbaz, M.D.

Associate Director for Epidemiologic Science
National Center for Infectious Diseases
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services

For Release on Delivery
Expected at 2:00 p.m.
Tuesday, December 14, 2004

Good afternoon Mr. Chairman and Members of the Committee. I am Dr. Rima Khabbaz, Associate Director for Epidemiologic Science of the National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC). I am accompanied today by Dr. Eric Mast, Acting Director of CDC's Division of Viral Hepatitis. We are pleased to be here today to describe the activities CDC has undertaken with partners to implement the *National Hepatitis C Prevention Strategy*, which this Committee was instrumental in initiating in 1998.

Background

Hepatitis C is a liver disease caused by the hepatitis C virus (HCV), which is found in the blood of persons who have this disease. Although hepatitis C can lead to cirrhosis or scarring of the liver, to liver failure, and liver cancer, the consequences of chronic liver disease from hepatitis C may not become apparent for 10 to 20 years, so many individuals infected with HCV are not aware of their infection. HCV infection is spread primarily by exposures that involve direct passage of blood through the skin, and it is the most common chronic bloodborne infection in the United States. About 4 million Americans have already been infected, of whom approximately 3 million are chronically infected, and about 30,000 Americans become newly infected each year. Unlike hepatitis A and hepatitis B, there is no vaccine to prevent infection with HCV.

Risk Factors Associated with HCV Infection

Before blood donor testing for non-A, non-B hepatitis became available beginning in the mid-1980s, and then a specific test for HCV infection beginning in 1990, blood transfusions accounted for 10-25 percent HCV infections. However, specific testing of blood donors has reduced the risk of infection from a unit of blood to less than one in 1,000,000 units transfused.

Injection drug use is now the risk factor for infection among about 50 percent of persons with past HCV infection, and since the mid-1980s, injection drug use accounts for approximately two-thirds of new infections among Americans. Of persons injecting drugs for at least 5 years, 60-80 percent are infected with HCV, a risk that is 2 to 3 times higher than for the human immunodeficiency virus (HIV). This high rate of infection accounts for the 15-30 percent prevalence of HCV infection that has been found among inmates of correctional facilities. Other risk factors for infection include occupational exposure to blood through a needle stick from an infected person, transmission to an infant from an infected mother, and less efficiently through sex with an infected sex partner.

Consequences of Infection with HCV

Approximately 75-85 percent of persons with an acute hepatitis C virus infection develop a chronic infection, and about 60-70 percent of those persons develop chronic hepatitis. Lower rates of chronic infection and liver disease appear to occur among persons who were infected as children.

Over a period of 20 to 30 years, cirrhosis of the liver occurs in 10-20 percent of persons with chronic hepatitis C virus infection and liver cancer developing in 1-5 percent of them. Surveillance studies conducted by CDC and the National Institutes of Health (NIH) show that HCV accounts for 40-60 percent of chronic liver disease in the United States. Chronic liver disease is the tenth leading cause of death among adults in the United States, and HCV causes between 8,000 and 10,000 of these deaths each year. HCV is the most frequent indication for

liver transplantation in this country; the number of patients on transplant waiting lists has doubled in the past 5 years, and about 50 percent of these patients die while awaiting liver transplant.

About one quarter of HIV-infected persons in the United States are also infected with HCV. HCV is transmitted primarily by large or repeated direct exposures to contaminated blood. Therefore, coinfection with HIV and HCV is common among HIV-infected injection drug users (IDUs). Coinfection is also common among persons with hemophilia who received clotting factor concentrates before concentrates were effectively treated to inactivate both viruses (i.e., products made before 1987). As highly active antiretroviral therapy (HAART) and preventive treatment of opportunistic infections increase the life span of persons living with HIV, HCV-related liver disease has become a major cause of hospital admissions and deaths among HIV-infected persons. Persons living with HIV who are not already coinfected with HCV can adopt measures to prevent acquiring HCV. Such measures will also reduce the chance of transmitting their HIV infection to others.

Treatment of Chronic HCV Infection

Current antiviral treatment completely eliminates HCV infection in 50-55 percent of selected patients, with 95 percent of those remaining virus free for at least 5 years. While antiviral therapy is indicated for many patients with chronic HCV infection, treatment is less effective and may not be indicated for patients with severe liver disease. Also, alcohol abuse appears to worsen the outcome of HCV, and antiviral treatment is more difficult among persons with ongoing abuse.

In addition to the benefits of antiviral treatment, patients with chronic HCV infection can benefit from counseling, immunizations, and other services to prevent progression of chronic liver disease. Because alcohol use is one of the most important contributing factors to progression of chronic liver disease in HCV-infected persons, it is important to identify infected persons as early as possible so that they can be counseled to limit alcohol consumption. In addition, persons with HCV should be vaccinated against diseases, including hepatitis A and hepatitis B, that may produce further liver injury or increase their risk of death.

CDC's Current Prevention and Control Efforts

Identification of HCV-infected persons and prevention of new infections are the major objectives of the *National Hepatitis C Prevention Strategy.* Identification of infected persons provides the opportunity for medical evaluation to: 1) determine the extent of their chronic liver disease, 2) determine if they are candidates for antiviral therapy, 3) determine if they need treatment for other conditions such as alcohol or drug abuse that will worsen their HCV, and 4) provide health education about how to prevent HCV transmission to others.

Identification of HCV infected persons, as well as persons at risk of HCV infection, is best achieved through the integration of hepatitis prevention services into community-based clinical and public health programs that serve at-risk persons. Because the majority of persons with HCV do not have symptoms of liver disease, their identification requires that testing be conducted on persons with risk factors for infection. CDC has conducted a number of community-based demonstration projects – the Viral Hepatitis Integration Projects, or VHIPs --

which have shown the feasibility and effectiveness of including hepatitis prevention services in a variety of clinical and public health settings. I will now highlight some specific components of the *National Hepatitis C Prevention Strategy*.

Health Communications: CDC has developed evidence-based guidelines for identification and testing of persons at risk of hepatitis C. In addition, CDC has provided a broad range of materials about hepatitis C for health care professionals and the public. Examples include web-based continuing medical education programs for health care professionals, a *Hepatitis C Toolkit* for primary care providers and their patients, and health education materials for high school teachers. These materials are available on CDC's web site and can be found at: http://www.cdc.gov/ncidod/diseases/hepatitis. CDC has also funded 12 viral hepatitis education and training cooperative agreements with academic centers, health departments and non-governmental organizations.

Community-based Prevention Programs: To accelerate the integration of hepatitis C testing, counseling and referral for medical evaluation into community-based programs that provide clinical and public health services, CDC has made funding available for Hepatitis C Coordinators. Currently, there are 53 coordinators in States, large metropolitan areas, and in the Indian Health Service (IHS). One activity that coordinators have been involved in is the development of comprehensive State hepatitis C prevention plans. Currently, 23 States have a plan or are in the process of developing such a plan. In addition, CDC has funded the VHIPs in 21 State and local health departments and in the IHS to provide models and best practices for integration of viral hepatitis prevention services into clinical and public health programs, such as

those in STD clinics, drug treatment facilities, HIV/AIDS prevention programs, and correctional settings. Additionally, CDC, in collaboration with the IHS Division of Epidemiology, provides technical assistance to Tribes, IHS facilities, Urban Indian Health Programs, and other American Indian/Alaskan Native groups to implement hepatitis C prevention activities.

Surveillance and Program Evaluation: Since 2003, chronic HCV infection has been a condition that is reportable by States to CDC. In 2003, 19 States submitted case reports. CDC has also developed surveillance guidelines for case investigation and follow-up of persons with chronic HCV infection. CDC will continue to work to develop and maintain enhanced national surveillance systems in order to monitor the effectiveness of hepatitis C prevention efforts. In addition, a study is underway to evaluate the effectiveness of the VHIPs and determine future directions for such demonstration projects.

Research: There continue to remain a number of unanswered questions concerning the epidemiology and natural history of HCV infection that need to be answered to develop interventions to prevent transmission of HCV and to prevent disease progression among persons with chronic infection. Priority areas in which studies are underway or in the planning stages include those that determine: 1) incidence and risk factors for HCV transmission among household contacts of infected persons; 2) risk factors for transmission from mother to infant at birth; 3) risk of infection from intranasal cocaine use, tattooing, and body-piercing; 4) prevalence and incidence of infection in incarcerated populations; 5) risk of infection among steady heterosexual partners of HCV-infected persons; 6) risk factors for infection among persons on chronic hemodialysis; 7) the dynamics of HCV acquisition among injection drug users and the

effectiveness of harm reduction strategies in preventing infection; 8) disease burden, including chronic liver disease and liver cancer mortality; and 9) risk factors for health care related transmission.

In conclusion, since 1998, there has been considerable progress made in raising awareness about the prevention of hepatitis C both among healthcare providers and the public. In addition, many States have initiated hepatitis C prevention programs, which are being facilitated by the federally funded Hepatitis C Coordinators.

To help us make further improvements in this area, CDC has established a National Viral Hepatitis Roundtable in conjunction with representatives from national voluntary health organizations, nongovernmental organizations, professional societies, health insurers, industry, and other governmental agencies. The Roundtable is designed to coordinate efforts by CDC and our partners to address hepatitis C and other forms of viral hepatitis. It helps to make sure efforts of CDC and its partners are targeted and not duplicated, so we can all make maximum use of our resources.

Thank you very much for this opportunity to update you on what has happened with hepatitis C prevention since this was last addressed by this Committee. I will be happy to answer any questions you may have.

RIMA KHABBAZ, M.D.

Associate Director for Epidemiologic Science
National Center for Infectious Diseases (NCID)
Centers for Disease Control and Prevention
Department of Health and Human Services

Dr. Khabbaz received her B.S. in 1975 and her M.D. in 1979 from the American University of Beirut (AUB) in Beirut, Lebanon. She first joined CDC as an Epidemic Intelligence Officer in 1980 after 2 years of internal medicine training at the AUB Medical Center in Beirut. She subsequently completed her residency in internal medicine at the Union Memorial Hospital in Baltimore and a fellowship in infectious diseases at the University of Maryland. She is board certified in Internal Medicine. During her CDC career, she has worked primarily in the areas of infection control in healthcare settings, viral infections including non-HIV retroviruses and hantavirus, and blood safety. She is currently Associate Director for Epidemiologic Science in the National Center for Infectious Diseases (NCID), CDC, and before that was Deputy Director of the Division of Viral and Rickettsial Diseases, NCID for 5 years. Her interests include emerging infections, viral diseases, blood safety, food safety, and the transmissible spongiform encephalopathies. She played a leading role in developing CDC's programs related to blood safety and was active in enhancing DVRD's programs under the Food Safety Initiative. She is a fellow of the Infectious Disease Society of America (IDSA), and a member of the American Epidemiologic Society, the American Society for Microbiology, and the American Society of Tropical Medicine and Hygiene. She served on the Blood Product Advisory Committee of the Food and Drug Administration from 1995-1999, and on the IDSA's Annual Meeting Scientific Program Committee from 1999-2002. She is the author of over 100 research and review papers including book chapters. NCID is currently working to address domestic and global challenges posed by emerging infectious diseases and the threat of bioterrorism.

December 2004

ERIC E. MAST, M.D., M.P.H.

Acting Director, Division of Viral Hepatitis
National Center for Infectious Diseases
Centers for Disease Control and Prevention
Department of Health and Human Services

Dr. Mast is a graduate of the University of Illinois College Of Medicine and the Harvard School of Public Health. He completed a pediatric residency at the University of Wisconsin Hospital and Clinics and is board certified in pediatrics. He joined CDC in 1987 as an Epidemic Intelligence Service Officer assigned to the Wisconsin Department of Health and Human Services. Since 1990, Dr. Mast has been working in the Division of Viral Hepatitis in a variety of positions including Chief of the Hepatitis Surveillance Unit, Medical Officer assigned to the Expanded Programme on Immunization at the World Health Organization, Acting Associate Director for Global Health, and Chief of the Prevention Branch. He is an author of more than 70 scientific manuscripts. His primary area of expertise is prevention and control of viral hepatitis. Dr. Mast is also an officer in the Commissioned Corps of the United States Public Health Service.

December 2004